

## **REMARKS**

Claims 1-12 are currently pending in the application. Claims 1 and 9 are in independent form.

The Office Action has indicated that there are sequences within the specification that do not include sequence identification numbers. Specifically, that Table 5 has a full length sequence and there is no legend to the Table, nor is there a Sequence ID Number. Enclosed herewith is a new Table 5 with the appropriate Sequence ID Number. It is respectfully submitted that at page 7, line 25, there is indicated that Table 5 is a sequence of *C.perfringens* (ORF) 325 sequence. Additionally, claim 9 has been amended to remove reference to SEQ ID No: 15. Accordingly, reconsideration of the objections are respectfully requested.

Claim 9 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Namely that there is reference in claim 9 to sequences that are not present in the application. Claim 9 has been amended in order to further prosecution to properly list the sequence numbers and reconsideration of the rejection is respectfully requested.

Claims 1 and 2-4 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Office Action has held that the claims include new subject matter, which was not described in the specification as filed. The claim recites that the polypeptides have 90% sequence homology to SEQ ID Nos: 1-10 and that the specification does not provide support for this statement. It is respectfully submitted that the sequences disclosed have a percent homology of at least 90%. Additionally, that there is disclosed on page 7 of the specification as filed that homology must be at least 80% and can approach 95% homology to the  $\alpha$ -N-acetylgalactosaminidase. However, in order to further prosecution, such reference to the homology has been canceled without prejudice,

thereby rendering the present rejection moot. Reconsideration of the rejection is respectfully requested.

Claims 1-4 and 9 stand rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for a single purified NAG purified from *C.perfringens* comprising amino acid sequence 11 does not reasonably provide enablement for any homologs having at least 90% homology to the peptide sequences set forth in SEQ ID Nos: 1-11 or functional analogs of the same. In order to further prosecution, the claims have been amended to more specifically recite that the sequence must be one selected from the group of sequences 1-11 and as such, reconsideration of the rejection is respectfully requested.

Claims 1-4 and 9 stand rejected under 35 U.S.C. §112, first paragraph, as containing subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Again, there is reference made to the homologs recited in the pending claims. In order for the prosecution, the claims have been amended to remove language related to homologs and reconsideration of the rejection is respectfully requested.

Claims 1-4 and 9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by the Levy et al article. Reconsideration of the rejection under 35 U.S.C. § 102(b) as being anticipated by the Levy et al article, as applied to the claims, is respectfully requested.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

The Office Action states that the Levy et al reference teaches an 8,000 fold purification of  $\alpha$ -N-acetylgalactosaminidase from *Clostridium perfringen*. The Office Action concludes that since the term "sialidase" is known as the alternative name for "neuraminidase" it is clear that neuraminidase, as well as other impurities were removed from the  $\alpha$ -N-acetylgalactosaminidase by the methods disclosed in the Levy et al reference. However, when read more specifically, the Levy et al reference teaches a method of purification that results in a preparation contaminated with multiple species of enzyme.

In the Levy et al article, it is postulated that the  $\alpha$ -N-acetylgalactosaminidase is a multi-enzyme complex that needs to be dissociated. In the final "dissociated" preparation they measure 0.1%, 1.9%, and 1.2% contamination with neuraminidase,  $\beta$ -galactosidase, and  $\beta$ -N-acetylglucosaminidase, respectively. Furthermore, in the SD-PAGE of their preparation, there is revealed multiple bands of  $\alpha$ -N-acetylgalactosaminidase activity along with several other protein bands. This is in contradistinction with the purified enzyme of the presently pending independent claims, wherein only one band is found on the SDS-Page of the final enzyme. This band is  $\alpha$ -N-acetylgalactosaminidase. Further, there is no detectable  $\beta$ -galactosidase or  $\beta$ -N-acetylglucosaminidase activity.

In direct comparison, the presently pending independent claims claim an enzyme that contains therein less than 0.8 ng of neuraminidase as detected per milligram of pure  $\alpha$ -N-acetylgalactosaminidase. In comparison, the enzyme conglomeration of the Levy et al article contains approximately 62 ng of neuraminidase. Accordingly, the enzyme of the presently pending independent

claims has at least 77-fold greater neuraminidase removal than that of the Levy et al article.

Further, the Levy et al. data is converted from  $\mu$ moles of substrate dehydrolyzed per hour to  $\mu$ moles hydrolyzed per minute. The Levy et al preparations have a specific activity of 17.4 compared to the present mean activity of 42.4 for the enzyme of the presently pending independent claims. Given its explicit teaching there is no disclosure of the enzyme recited in the presently pending independent claims. Since, the Levy et al article does not disclose the enzyme recited in the presently pending independent claims, reconsideration of the rejection is respectfully requested.

The remaining dependent claims not discussed above are ultimately dependent upon at least one of the independent claims discussed above. No prior art reference makes up for the deficiencies of that reference as applied against the independent claims as no prior art reference discloses or suggests the invention as set forth in the claims as discussed in detail above.

In conclusion, it is respectfully submitted that the presently pending claims are in condition for allowance, which allowance is respectfully requested. Applicant respectfully requests to be contacted by telephone if any remaining issues exist.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC

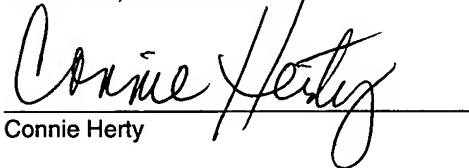


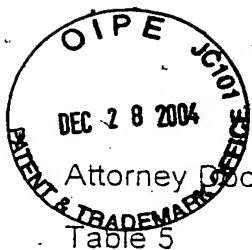
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Attorney Docket No. 0994.00134

Table 5

SEQ ID NO: 11

1 mkvlgnyiqr othydgksfy tsflnpiln ceilvhtqne fiyfvdger  
51 lpssemanvei kqseqllvv nfkdnlsve vnyfvenkvi nkkltvfnce  
101 krnyidcdt fefedtnniy ypkkqmike mgnfngyve lgqpiyaksl  
151 fngmefpmge nriqerkyfs ryyygksvek rldihsaig sapekskeki  
201 qasffeyika islpafkq ynswydhmIn imdsiiksf leinrgfny  
251 gitldafvvd dgwanyesvw efndkfpnel kdisecvknI gstlgwigp  
301 rsgyngtqvt msdwleknkd lnigsknkis ndvngdfny lrknnkekmlc  
351 yqskydisyw kidgmllkpd tedesgpygm hntavyefm islnelree  
401 rgekswinal tsynpspwf lkwnslwiq tsqdygtpn ggndiqkmit  
451 yrdsqyyefl ierdiqlplc slynhepiya esasmwyldh qiycsieefk  
501 eylvfiatrg nafwefyysy smfdderwev naqaikwiee nypilkstf  
551 fgtkpslmgv yggyoqsdsg sksiisfmp sdeiksykle niepkkydvv  
601 lgnknykvfc dgsvevklmp keitiilksk

Table 5 continued

SEQ ID NO: 12

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 108061 aaaaagtttt tataccacat cattttttaa tcctattcta aatgaagaaa tattagtcca  
 108121 tacacaaaat gaatttatta tctattttgt agatggagaa acattacott cttctgagat  
 108181 gaatgtggag attaagaagc aaagtgaaca acttttagtg gtgaatttta gtaaagataa  
 108241 cttatctgtt gaagtcaatt attttgtgga aaataagggt ataaataaaa agctaacagt  
 108301 tttcaattgt tgtaaacgta ttaattatat tgactgtgat acttttgaat ttgaggatac  
 108361 taataatata tattacccta aaaaacagaa taatataaag gaaatgggga attttaacgg  
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 108481 tcctatggga gaaaatcgta ttcaagaaag aaagtatttc tcaagggtatt attatggaaa  
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 108601 aaaagaaaaa attcaagctt cattttttga gtatattaaa gctatatctt tgccagctac  
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 108781 ctttgtagtt gatgatggtt gggctaatta tgaaagtgtt tgggaattta atgataagtt  
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 108961 aaaaaataag gatttaaaaca taggatctaa aaataaaaat tctaatagat taaatgtagg  
 109021 agactttaat tatcttagaa agatgaaaga aaaaatgtta gagtaccaa gcaaatatga  
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 109201 gtttaagagaa gaaagaggag aaaagagttt ttggatcaat cttacatctt atgttaatcc  
 109261 tagcccttgg ttttcaaagt gggtaaatag tctttggatc cagacttcac aagatgttgg  
 109321 ctttactcca aatggaggaa atgatattca gaaaatgata acatatcgtg attctcaata  
 109381 ttatgaattc ttgattgaaa gagatattca acttccatta tgtagcttat ataactatga  
 109441 acctatttat gcagagtctg caagtatgtg gtatttagat catcaaatct attgttctat  
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 109561 ttattattct tattccatgt ttgatgatga acgttgggaa gtaaaccgac aagccattaa  
 109621 gtggattgag gaaaattatc caatattaaa aaatagtact tcttttgga caaagcctag  
 109681 ccttatggga gtatattgat actattgtca atcagattct ggttcaaaat caattatttc

Table 5 continued

109741 atttagaaac ccatcagatg aaattaaatc ttataaactt gagaatatag aaccaaagaa

109801 atatgacgta gttctaggca ataaaaatta taaagtcttc gaagatgggt ccgttgaagt

109861 taaattaaat cctaaagaaa ttattatact taagagttaa taa